

**Remarks**

Claims 1-3, 6, 7, 9-15, and 17-22 are pending and at issue in this application. Claims 1, 2, 6, 7, 9-11, 13, 15, 18, and 19 have been amended and new claims 21 and 22 have been added herein. Support for the amendments to claims 1, 13, and 18 may be found in the specification at least in paragraphs [0071]-[0073] and in FIGS. 11-13. Support for the amendments to claims 2, 15, and 19 and for newly added claim 21 may be found in the specification at least in paragraph [0075] and FIG. 16. Support for newly added claim 22 may be found in the specification at least in paragraphs [0052]-[0055] and FIGS. 2A, 2B, 3A, and 3B. Claims 9-11 have been amended to correct dependency thereof. Claims 6 and 7 have been amended to correct improper antecedent basis thereof. No new matter has been entered by the claim amendments. A new search should not be required as a result of the claim amendments or the newly added claims, and the applicants respectfully request that the claim amendments made herein after a final rejection be entered into the record.

Claims 1-3, 13-15, and 17-20 stand rejected as obvious over Palmaz et al. (WO 01/74274) ("Palmaz") in view of Casey, II et al. (US 2004/0019375) ("Casey"), and further in view of Drasler (6,287,335) ("Drasler"). Claims 6, 7, and 9-12 stand rejected as obvious over Palmaz, Casey, and Drasler, and further in view of one of Van Schie (6,974,471), Kula et al. (6,325,825) or Banas et al. (5,749,880). Applicants traverse the rejections of claims 1-3, 6, 7, 9-15, and 17-20 as obvious.

**Summary of Examiner's Interview**

The undersigned thanks the examiner for granting a telephonic interview after final rejection. During the telephonic interview held on June 21, 2010, the undersigned and examiner discussed claim amendments that define locations of microperforations with regard to structure of the implantable graft as amplified herein in amended claims 1, 13, and 18. The examiner indicated that the claim amendments would be considered; however, no agreement was reached regarding allowability of the claims.

## **Arguments**

### **Claims 1-3, 13-15, and 17-20 stand rejected as obvious under 35 USC § 103 over Palmaz in view of Casey, and further in view of Drasler.**

#### **A. Claims 1-3 and 17-20**

Independent claim 1 has been amended to include “circumferential corrugations defined by a radially undulating pattern of wall segments disposed between longitudinally alternating radially extending peaks and valleys in each of the luminal wall and abluminal wall surfaces of the body member and a plurality of microperforations disposed through the wall segments.” Claim 18 has been amended to include “a plurality of annular ridges defined by a radially undulating pattern of wall segments disposed between longitudinally alternating radially extending peaks and valleys in each of the luminal wall and abluminal wall surfaces of the body member, wherein a plurality of microperforations is disposed through the wall segments.” Both claims 1 and 18 recite “a body member comprising a film selected from the group consisting of metallic and pseudometallic materials.”

Palmaz discloses openings disposed through “the web regions of the inventive web-stent, the graft regions of the inventive stent-graft, and the inventive graft.” (Page 20, lines 26-28). In all instances, the disclosed openings of Palmaz are disposed through portions of a web or graft that are oriented generally parallel with a longitudinal axis of the endoluminal device such that the openings are oriented generally normal to the longitudinal axis. Palmaz does not disclose or suggest a plurality of microperforations disposed through a wall segment disposed between longitudinally alternating radially extending peaks and valleys in each of luminal and abluminal wall surfaces of the body member, as required by claims 1 and 18.

Casey discloses a sectional crimped graft made from a non-metallic material that is formed by applying mechanical or fluid force to cause the graft to conform to the shape of a mandrel. Further, Casey does not disclose or suggest microperforations disposed through the non-metallic graft.

Drasler does not disclose or suggest wall segments disposed between longitudinally alternating radially extending peaks and valleys in each of luminal and abluminal wall surfaces of a body member, let alone microperforations disposed through such wall segments. In fact, Drasler teaches away from such microperforations:

[t]o prevent blood cellular elements from passing through the leakage sites 495, the gaps cannot be significantly larger than the cellular elements found in the blood. With small leakage sites 495, red blood cells and plateletes can become trapped and create thrombosis that will prevent leakage from that gap or leakage site. Red blood cells are typically 8 micrometers in the larger diameter of the red blood cell.

(Column 49, lines 24-31, emphasis added).

Thus, Drasler stresses the importance of preventing leaks (of blood cellular elements) through the intravascular tubular member, stating that any gaps in the intravascular tubular member ***“cannot be significantly larger than the cellular elements found in the blood.”*** Further, Drasler discloses that “leakage or seepage” of blood through the vascular tubular member is undesirable, stating that “[t]o ***reduce or eliminate small pores*** at the crossover points a tubular double weave is preferred when a metal strand is woven. (Column 8, lines 24-26, emphasis added, *See also, e.g.*, “provide a leak-tight seal” at Column 9, line 7; “leak-free attachment” at Column 9, line 24; “leak-tight attachment” at Column 9, line 64; etc.). In diametric opposition, the current application teaches that “microperforations may be such as to permit cellular migration through each opening. . . . For other applications, moderate amounts of fluid flow through the plurality of deformed or un-deformed microperforations may be acceptable.” (Paragraph [0020]). Thus, Drasler expressly teaches away from an implantable medical graft comprising a plurality of microperforations disposed through a wall thickness of the body member, as required by independent claims 1 and 18. “It is improper to combine references where the references teach away from their combination.” (MPEP § 2145(X)(D)(2), citing *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983)). It is therefore improper to combine Drasler with Palmaz because Drasler teaches away from such combination.

Further, a plurality of microperforations disposed through a wall thickness of the intravascular tubular member of Drasler would render the intravascular tubular member unsatisfactory for its intended purpose by allowing blood cellular elements to pass through the intravascular tubular member. “If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” (MPEP § 2143.01(V), citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). For at least the reasons above, it is improper to combine Drasler with Palmaz because Drasler teaches away from such combination, and because such modification would render Drasler unsatisfactory for its intended purpose.

Regarding a combination of Casey and Drasler, a person of ordinary skill in the art of making a flexible graft from metallic or pseudometallic materials would not have a reason to combine Casey's non-metallic graft lacking microperforations with the metallic structures disclosed in Palmaz. Even allowing for such improper combination, Casey and Palmaz, considered individually or collectively do not disclose or suggest a structure comprising a radially undulating pattern of wall segments disposed between longitudinally alternating radially extending peaks and valleys in each of the luminal wall and abluminal wall surfaces of the body member and a plurality of microperforations disposed through the wall segments, as required by claims 1 and 18. All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). MPEP § 2143.03. It follows that independent claims 1 and 18 cannot be rendered obvious by a combination of Palmaz, Casey, and Drasler. Further, all claims depending from independent claims 1 and 18 are also nonobvious. Applicants respectfully request that the examiner withdraw all rejections of claims 1-3, 6, 7, 9-12, and 17, and claims 18-20, and timely issue a notice of allowability therefor. New claims 21 and 22 are dependent on independent claim 1 and should also therefore be in condition for allowance, such allowance respectfully being requested.

#### **B. Claims 13-15**

Claim 13 recites providing a generally cylindrical substrate having a plurality of circumferentially extending continuous undulations defined by a radially undulating pattern of surfaces disposed between longitudinally alternating radially extending peaks and valleys, vacuum depositing a graft-forming material onto the generally cylindrical substrate, releasing the deposited graft-forming material from the substrate to form a implantable medical graft including circumferential corrugations defined by a radially undulating pattern of wall segments disposed between longitudinally alternating radially extending peaks and valleys, and forming a plurality of microperforations disposed through the thickness of the wall segments. Palmaz discloses an endoluminal implantable device including vacuum deposited structural members and interstitial web regions between the structural members. Palmaz does not disclose or suggest providing a generally cylindrical substrate having a plurality of circumferentially extending continuous undulations defined by a radially undulating pattern of surfaces disposed between longitudinally alternating radially extending peaks and valleys, releasing the deposited graft-forming material

from the substrate to form a implantable medical graft including circumferential corrugations defined by a radially undulating pattern of wall segments disposed between longitudinally alternating radially extending peaks and valleys, and forming a plurality of microperforations disposed through the thickness of the wall segments, as required by claim 13.

As discussed hereinabove in section A, Drasler expressly teaches away from a graft having microperforations as disclosed in the current application, and modification of Drasler to include such microperforations would render Drasler unsatisfactory for its intended purpose. Thus, there is no reason to modify Drasler to include microperforations, and it is improper to combine Drasler with Palmaz.

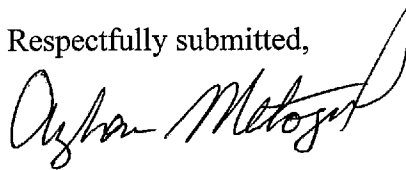
Casey discloses a sectional crimped graft made from a non-metallic material that is formed by applying mechanical or fluid force to cause the graft to conform to the shape of a mandrel. Casey does not disclose or suggest vacuum depositing a graft-forming material onto a generally cylindrical substrate, releasing the deposited graft-forming material from the substrate to form a implantable medical graft including circumferential corrugations defined by a radially undulating pattern of wall segments disposed between longitudinally alternating radially extending peaks and valleys, and forming a plurality of microperforations disposed through the thickness of the wall segments.

As noted above, regarding a combination of Casey and Drasler, a person of ordinary skill in the art of making a flexible graft from metallic or pseudometallic materials would not have a reason to combine Casey's non-metallic graft lacking microperforations with the metallic structures disclosed in Palmaz. Even allowing for such improper combination, Casey and Drasler, considered individually or collectively, do not disclose or suggest releasing the deposited graft-forming material from the substrate to form a implantable medical graft including circumferential corrugations defined by a radially undulating pattern of wall segments disposed between longitudinally alternating radially extending peaks and valleys, and forming a plurality of microperforations disposed through the thickness of the wall segments. It follows that independent claim 13 cannot be rendered obvious by a combination of Palmaz, Casey, and Drasler. Further, claims 14 and 15 depending from independent claim 13 are also nonobvious. Applicants respectfully request that the examiner withdraw all rejections of claims 13-15, and timely issue a notice of allowability therefor.

**Fees**

No fees are believed due with this Response, however, the Director is hereby authorized to charge any under payment of fees, or credit any overpayment to Deposit Account No. 18-2000, of which the undersigned is an authorized signatory.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Ayhan Mertogul", written in a cursive style.

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